

K961522

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ATTACHMENT 11

510(k) SUMMARY

Submitting Company: SYNVASIVE Technology, Inc.  
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Common Product Name: Kirschner Wires (K-Wires) and Steinmann Pins

Classification Name: Smooth or Threaded Metallic Bone Fixation  
Fastener (per 21 CFR 888.3040)

Product Description: The subject devices (K-Wires and Steinmann Pins) are stainless steel fixation devices which draw bone fragments together in order to facilitate healing. They will be supplied both as sterile and non-sterile devices and will be labeled for single use.

Intended Use: The fixation devices are designed to draw two or more bone fragments together in order to facilitate healing. The fixation devices are driven through the bone fragments using a powered rotary device. The fixation devices are typically left implanted in the body to provide fixation while the bone mends.

Substantial Equivalence: The fixation devices are substantially equivalent to standard K-Wires and Steinmann Pins legally marketed by many companies including DePuy, Howmedica, MicroAire, and Zimmer.

Technological Characteristics: The fixation devices have the same technological characteristics as all of the predicate devices.

Safety and Effectiveness Testing: All materials used in the fixation devices conform with ASTM specifications for medical device use. Material specifications are tested on a design basis and certificates of conformance to specifications are supplied with each material batch.